

WHAT CAN BE DONE?

I think we can expect little stimulus for correcting the inadequacies of our present system from organized medicine. Physicians' organizations and our disease-oriented foundations have been sweethearts and financial dependents of the drug industry too long to desire any effective change: drug testing must be cleaned up.

Tests are not getting any better. In 1960, McMahon and Daniel, reporting in the Canadian Medical Association Journal, found only five per cent of published trials met even the crudest scientific standards. The trials I reviewed in 1967 were not any better. The doctrine that other parts of medicine are science, but that drug testing is a mystic art which can be performed by only uncontrolled dabblings of so-called experienced clinicians is a sham. Further, it is ethically unacceptable to subject human beings to dangerous drugs unless the experiments are scientifically excellent. The FDA has made some feeble beginnings, but society must demand that only scientific experiments which produce meaningful numerical results be acceptable. Drug testing should be taken completely out of the hands of the pharmaceutical industry. They have repeatedly been guilty of irresponsible optimism about drugs, and their use of paid testimonials is a shallow substitute for good scientific trials.

The distorted Madison Avenue approach used in the promotion and advertising of drugs must be completely eliminated. How can society, which spends only \$250 million on medical education, idly stand by and watch the drug industry spend \$900 million annually on the post-graduate miseducation of physicians? The public eventually foots not only the bill for the advertising, but also the bill for the new, dangerous, fancy substitutes for the old established remedies. The annual \$5 billion drug bill could easily be reduced by \$2 billion. Claims that advertising is necessary, and that promotional efforts serve a useful purpose are a joke. The physicist would hardly think of announcing the discovery of a new particle by an aggressive advertising campaign. Why can't physicians get information on new drugs from scientific journals? This is exactly the manner in which they learn about the latest observations on complications of pneumonia, or electrocardiographic changes in heart block.

New legislation is needed. The present laws require only that a drug be safe and effective as labeled. A drug must meet no pressing need, and a more toxic substitute for a standard drug can be marketed. The penalties for violations of the present laws should be increased. Convictions for serious fraud in advertising may carry only a maximum penalty of \$1,000 under the present legislation. The penalties are so trivial and prosecution so infrequent, that huge settlements in personal liability suits resulting from drug injuries have a much greater influence on controlling the drug companies' advertising than does federal legislation. A lawsuit to attempt to collect damage for a death is a very poor substitute for preventing the death.

A STRONGER FDA

NIH should surely expand its work in clinical pharmacology, making every effort to upgrade it as a precise science. But simply providing more support is not enough. The public must be assured that investigators who receive public grants are loyal to the public cause, and are not involved in any financial conflicts of interest.

The FDA likewise should be further strengthened. FDA officers receive a constant diet of abuse and rarely if ever congratulation for the vital public service they perform. All of us have a role to perform in refuting frequent unfounded attacks on officials of this agency. At the same time, every scientist should in any way possible prod the FDA to improve its scientific status and the quality of its staff.

Scientists must urge the public not to accept excuses for drug catastrophes or for excessive medical costs due to drugs. The scientist must particularly guard against the jargon games used by the pharmaceutical industry in obscuring any problem. Endless demands for proof positive, suggestions for long-term studies, and frightening announcements that any action will destroy the entire pharmaceutical industry are all part of this game. Dr. I. D. J. Bross, in *Science*, has particularly warned against the fallacies: